

Treatment of erectile dysfunction with Extracorporeal Shockwave Therapy (ESWT). A prospective, randomised, double-blind, placebo-controlled study.

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Objective: The aim is to demonstrate that penile shockwave application in patients with erectile dysfunction (ED) of vascular origin leads to a greater increase in potency than in the control group.

Methods: A prospective, randomised, blinded, placebo- controlled study conducted from 2012- 2013. The study enrolled 112 male participants unable to fulfil an intercourse either with or without medication. All participants had ED >six months. Seven of the patients were excluded due to the protocol.

Each patient provided their full medical and sexual history. After the initial interview, they were randomly assigned either Extracorporeal Shockwave Treatment (ESWT) (n = 51) or placebo (n = 54). Patient's received five treatments over a five-week period, blinded for the patients and physicians. Assessment of ED was performed at screening, 5, 12 and 24 weeks after treatment by interview and validated sexual function questionnaires: **Erection Hardness Score** (EHS) and International Index of Erectile Function (IIEF). The chi- squared test #2 was used to analyse differences between patient groups. Results: All enrolled patients but two completed the study. The median age was 60 years (range 37- 80 years). Both groups showed similar characteristics in co- morbidities and use of PDE- 5 inhibitors.

Over the five-week treatment period a *significant number of patients from the ESWT group improved their **Erection Hardness Score***. Twenty- nine patients (56.9 %) had an EHS of 3- 4, allowing full sexual intercourse without medication compared to the placebo group, where only five (9%) showed similar results (p = 0.0001).

Conclusion: This study has shown that 59% of patients with ED of organic origin be treated alone by **Extracorporeal Shockwave Therapy** compared to the placebo group. At 24-week follow-up 12 patients (28.2%) still belonged to category 3- 4. The study showed the same response in the placebo group when it was treated with active ESWT. *Treatment is patient friendly and has no side effects.*